REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 1-17 are pending in the application. Claims 1-17 have been rejected. Claims 1, 3 and 7 have been amended.

Claims 2, 4-6 and 8-17 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in these claims to file divisional and/or continuation patent applications.

New claims 18 & 19 have been added in order to further define what the Applicants consider to be the invention. Applicants respectfully assert that no new matter has been added.

Applicants respectfully assert that the amendments to the claims add no new matter.

CLAIM REJECTIONS

35 U.S.C. § 112 Rejections

In the Office Action, the Examiner rejected claims 7-17 under 35 U.S.C. § 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner alleges that while being enabling for the treatment of a memory impairment or cognitive dysfunction, does not reasonably provide enablement for the treatment of Alzheimer's disease as well as the prevention of memory impairment or cognitive dysfunction, including, Alzheimer's disease.

Applicants respectfully note that Claim 7 was amended to recite "A method of treating or preventing a memory impairment or a cognitive dysfunction in a subject, comprising the steps of: providing to the subject, an effective amount of the composition of claim 1 and continuing said administration for a period of at least about six weeks, thereby stabilizing brain membranes and increasing brain DAG." Applicants note that as amended, claim 7 is fully enabled by the specification as is evident in, for example paragraph 0031, noting that under conditions of memory impairment, the compounds of the invention function to stabilize brain membranes, repair damaged membranes; and restore neuronal function. Moreover, as noted in paragraph 0029, incorporating fatty acids results in increased brain DAG. Taken together with paragraph 006, which notes that "Loss of cholinergic neurons within the nucleus basalis has been correlated with cognitive impairment and disease severity through studies conducted using postmortem tissue from AD patients.", the aforementioned disclosure clearly shows the benefit of administering the compositions described in the application in the treatment of memory impairment or a cognitive dysfunction resulting from AD *inter-alia*.

Accordingly Applicants respectfully assert that claim 7 as amended is enabled by the description and request the Examiner to remove the rejection of amended claim 7, under 35 U.S.C. § 112, first paragraph.

Claims 8-17 have been cancelled and therefore the rejection of claims 8-17 is moot.

35 U.S.C. § 102 Rejections

In the Office Action, the Examiner rejected claims 1 under 35 U.S.C. § 102(b), as being anticipated by Weiss (PTO-892 ref. u). Specifically, the Examiner asserts that Weiss teaches the administration of citicoline to treat a variety of diseases such as Alzheimer's disease as well as conditions related to decreased learning and memory. Applicants respectfully disagree.

Weiss is a review article citing over 180 other articles. Weiss does not teach or suggests a composition for treating or preventing memory impairment or cognitive dysfunction comprising citicoline, or a pharmaceutically-acceptable salt thereof, wherein said citicoline is metabolized to form cytidine, uridine, or choline; and linoleic acid, linolenic acid

or their active metabolites and their combination, as recited in amended claim 1. For a reference to anticipate a claim, the reference must teach all elements of the claim. Therefore, Weiss cannot anticipate claim 1, as amended. Accordingly, Applicants assert that claim 1 is allowable and respectfully request that the examiner withdraw the rejection of amended claim 1, under 35 U.S.C. § 102(b).

In the Office Action, the Examiner rejected claims 1-7, 11, 12 and 17 under 35 U.S.C. § 102(b), as being anticipated by Bradley et al of U.S. Patent No, 5,977,174 (the '174 Patent). Specifically, the Examiner asserts that the '174 patent that it is known in the art that citicholine and CDP-choline are neuroprotective agents, which can be used to treat neurodegenerative disorders involving loss of cognition, inter alia Alzheimer's disease, as well as the pharmaceutical compositions of neuroprotective agents along with pharmaceutically acceptable excipients and carriers, and modes of administration. Applicants respectfully disagree.

The '174 Patent discloses **covalent** DHA-choline **conjugates**, for treatment of stroke, as noted in Column 2, lines 59-61; "[T]he cholinergic agent preferably is conjugated directly to the fatty acid via the COOH of the fatty acid, without a linker" (emphasis added).

The '174 Patent does not teach or suggests a composition for treating or preventing memory impairment or cognitive dysfunction comprising citicoline, or a pharmaceutically-acceptable salt thereof, wherein said citicoline is metabolized to form cytidine, uridine, or choline; and linoleic acid, linolenic acid or their active metabolites and their combination, as recited in amended claim 1. For a reference to anticipate a claim, the reference must teach all elements of the claim. Therefore, the '174 Patent cannot anticipate claim 1, as amended. Accordingly, Applicants assert that claim 1 is allowable and respectfully request that the examiner withdraw the rejection of amended claim 1, under 35 U.S.C. § 102(b).

Since claims 3 and 7 depend directly from independent claim 1 as amended, they are likewise not anticipated the '174 Patent. Additionally, claims 2, 4-6, 11,12 and 17 were cancelled, making their rejection moot. Accordingly, Applicants respectfully assert that the '174 Patent to Bradley et al., does not anticipates the present invention, is improperly cited and request withdrawal of the rejection of amended claims 1, 3 and 7 under 35 U.S.C. § 102(b).

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 1 and 11 under 35 U.S.C. § 103(a), as being unpatentable over Weiss (PTO-892 ref. u). Specifically, the Examiner asserts that Weiss (PTO-892 ref. u) teaches the administration of citicoline to treat a variety of diseases such as Alzheimer's disease as well as conditions related to decreased learning and memory. The Examiner admits that Weiss, G. is silent regarding the period of administration of at least six weeks to the individuals in need thereof, but that the determination of a dosage having the optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug and therefore, the reference makes obvious the instant invention.

Applicants respectfully traverse the rejection because a prima facie case of obviousness has not been established.

Weiss (PTO-892 ref. u) does not teach or suggest all the limitations of amended claim 1(independent). Weiss (PTO-892 ref. u) has been discussed above and that discussion is applicable here.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since, Weiss (PTO-892 ref. u) does not teach or suggests all the elements of independent claim 1 as amended, the Examiner fails to establish a prima facie showing that Weiss (PTO-892 ref. u), teach or suggest every feature of amended claim 1. Additionally, claim 11 was cancelled, making its rejection moot.

In the Office Action, the Examiner rejected claims 1-17 under 35 U.S.C. § 103(a), as being unpatentable over Bradley et al. of US. Patent No. 5,977,174 (the '174 Patent) in view of von Borstel (PTO-892 ref. B, the '719 Publication). Specifically, the Examiner asserts that the '174 Patent teaches that it is known in the art that citicholine and CDP-choline are

neuroprotective agents, which can be used to treat neurodegenerative disorders involving loss of cognition, inter alia Alzheimer's disease and methods and compositions thereof using the same. Likewise, the Examiner asserts that the '719 Publication disclose of administering a pyrimidine nucleotide precursor in order to effectively treat neurodegenerative disorders, allegedly Alzheimer's disease. Accordingly, the Examiner alleges, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose"

Applicants respectfully traverse the rejection because a prima facie case of obviousness has not been established.

The '174 Patent does not teach or suggest all the limitations of amended claim 1(independent). The '174 Patent has been discussed above and that discussion is applicable here. Moreover, the '174 Patent teaches away from the administration of citicoline and linoleic and linolenic acid separately, as recited in Applicants amended independent claim 1, since the intended purpose of the invention disclosed and claimed in the '174 Patent is to provide **covalent** DHA-choline **conjugates**, for treatment of stroke. As noted in the '174 Patent, the purpose of conjugating the DHA to the drug of choice, is to assist in transport of the drug across the blood-brain barrier. Therefore, practicing Applicants invention as disclosed, would render the '174 Patent unsatisfactory for its intended purpose, making the modification suggested by the Examiner, improper (*See* e.g. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984), noting that "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.").

Likewise, the '719 Publication is unavailable. The defects of the '174 Patent were discussed above and the '719 Publication does not cure these defects. Moreover, the '719 Publication discloses compositions containing pyrimidine nucleotide precursors in amounts sufficient to treat symptoms resulting from mitochondrial respiratory chain deficiencies in subjects having pre-existing pathologies. There is no motivation to modify the compositions disclosed in the '719 to be administered to subjects without mitochondrial respiratory chain deficiencies, since in doing so, the principle of operation disclosed in the '719 would be changed. Therefore, the teachings in the '719 Publication alone are insufficient to render the claims of the

present Application, *prima facie* obvious. (*See* In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Neither the '174 Patent or the '719 Publication teach or suggest a composition for treating or preventing memory impairment or cognitive dysfunction comprising citicoline, or a pharmaceutically-acceptable salt thereof, wherein said citicoline is metabolized to form cytidine, uridine, or choline; and linoleic acid, linolenic acid or their active metabolites and their combination, as recited in Applicants' amended claim 1.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). None of the cited prior art, either alone or in combination teaches or suggests all the claim elements as recited in Applicants' amended independent claim 1. Thus, the Examiner's grounds for rejection are insufficient. Since claims 3 and 7 depend either directly or indirectly from independent claim 1 as amended, they contain all the limitations of amended independent claim 1 and are likewise allowable. Since claims 2, 4-6 and 8-17 are cancelled, their rejection is moot. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1, 3 and 7 under 35 U.S.C. §103(a).

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

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